

1 AMY W. SCHULMAN  
2 DLA PIPER LLP  
3 1251 Avenue of the Americas  
4 New York, NY 10020  
5 Telephone: (212) 335-4500  
6 Facsimile: (212) 335-4501  
7 amy.schulman@dlapiper.com

5 STUART M. GORDON (SBN: 037477)  
6 GORDON & REES LLP  
7 Embarcadero Center West  
8 275 Battery Street, Suite 2000  
9 San Francisco, CA 94111  
Telephone: (415) 986-5900  
Facsimile: (415) 986-8054  
sgordon@gordonrees.com

10 MICHAEL C. ZELLERS (SBN: 146904)  
11 TUCKER ELLIS & WEST LLP  
12 515 South Flower Street, Suite 4200  
13 Los Angeles, CA 90071-2223  
14 Telephone: (213) 430-3400  
15 Facsimile: (213) 430-3409  
16 [michael.zellers@tuckerellis.com](mailto:michael.zellers@tuckerellis.com)

14 Attorneys for Defendants  
PFIZER INC., PHARMACIA CORPORATION, AND  
G.D. SEARLE LLC

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

## SAN FRANCISCO DIVISION

NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiffs' Complaint as "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation (formerly known as "Monsanto Company"<sup>1</sup>) ("Pharmacia"), and G.D. Searle LLC ("Searle") (collectively "Defendants"), and file this Answer to Plaintiffs' Complaint ("Complaint"), and would respectfully show the Court as follows:

I.

## **PRELIMINARY STATEMENT**

The Complaint does not state in sufficient detail when Plaintiffs were prescribed or used Bextra® (valdecoxib) (“Bextra®”). Accordingly, this Answer can only be drafted generally. Defendants may seek leave to amend this Answer when discovery reveals the specific time periods in which Plaintiffs were prescribed and used Bextra®.

II.

## ANSWER

## **Response to Allegations Regarding Parties**

1. Defendants admit that Plaintiffs brought this civil action seeking monetary damages, but deny that Plaintiffs are entitled to any relief or damages. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance

<sup>1</sup> Plaintiffs' Complaint names "Monsanto Company" as a Defendant. Defendants state that in 1933, an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the agricultural business and does not and has not ever designed, produced, manufactured, sold, resold or distributed Bextra®. Given that Plaintiffs allege in their Complaint that Monsanto Company was involved in distributing Bextra®, *see PLAINTIFFS' COMPLAINT* at ¶ 6, Defendants assume Plaintiffs mean to refer to 1933 Monsanto. As a result, Pharmacia will respond to the allegations directed at Monsanto Company.

1 with its FDA-approved prescribing information. Defendants state that the potential effects of  
2 Bextra® were and are adequately described in its FDA-approved prescribing information,  
3 which was at all times adequate and comported with applicable standards of care and law.  
4 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damages,  
5 and deny the remaining allegations in this paragraph of the Complaint.

6 2. Defendants are without knowledge or information sufficient to form a belief as to the  
7 truth of the allegations regarding Plaintiff's age and citizenship, and, therefore, deny the same.  
8 Defendants are without knowledge or information sufficient to form a belief as to the truth of  
9 the allegations regarding whether Plaintiff used Bextra® and Plaintiff's medical condition, and,  
10 therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the  
11 Complaint.

12 3. Defendants are without knowledge or information sufficient to form a belief as to the  
13 truth of the allegations regarding Plaintiff's age and citizenship, and, therefore, deny the same.  
14 Defendants are without knowledge or information sufficient to form a belief as to the truth of  
15 the allegations regarding whether Plaintiff used Bextra® and Plaintiff's medical condition, and,  
16 therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the  
17 Complaint.

18 4. Defendants admit that Pfizer is a Delaware corporation with its principal place of  
19 business in New York. Defendants admit that Pharmacia acquired Searle in 2000 and that, as  
20 the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.  
21 Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted  
22 Bextra® in the United States, including California, to be prescribed by healthcare providers  
23 who are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
24 Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and  
25 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of  
26 such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in  
27 this paragraph of the Complaint.

28 5. Defendants admit that Searle is a Delaware limited liability company with its principal

Gordon & Rees, LLP  
275 Battery Street, Suite 2000  
San Francisco, CA 94111

1 place of business in Illinois. Defendants admit that, during certain periods of time, Bextra®  
2 was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted  
3 and distributed Bextra® in the United States to be prescribed by healthcare providers who are  
4 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
5 deny the remaining allegations in this paragraph of the Complaint.

6 6. Defendants admit that in 1933 an entity known as Monsanto Company (“1933  
7 Monsanto”) was incorporated under the laws of Delaware. On March 31, 2000, a subsidiary of  
8 1933 Monsanto merged with Pharmacia & Upjohn, Inc, and 1933 Monsanto changed its name  
9 to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company,  
10 was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company  
11 changed its name to Monsanto Company (“2000 Monsanto”). The 2000 Monsanto is engaged  
12 in the agricultural business and does not and has not ever manufactured, marketed, sold, or  
13 distributed Bextra®. The 2000 Monsanto is not and has never been the parent of either Searle  
14 or Pharmacia. As the 2000 Monsanto does not and has not ever manufactured, marketed, sold,  
15 or distributed Bextra®, Defendants therefore state that the 2000 Monsanto is not a proper party  
16 in this matter. Defendants deny the remaining allegations in this paragraph of the Complaint.  
17 Defendants state that the response to this paragraph of the Complaint regarding Monsanto is  
18 incorporated by reference into Defendants’ responses to each and every paragraph of the  
19 Complaint referring to Monsanto and/or Defendants.

20 7. Defendants admit that Pharmacia is a Delaware corporation with its principal place of  
21 business in New Jersey. Defendants admit that, during certain periods of time, Pharmacia  
22 marketed and co-promoted Bextra® in the United States, including California, to be prescribed  
23 by healthcare providers who are by law authorized to prescribe drugs in accordance with their  
24 approval by the FDA. Defendants state that Plaintiffs’ allegations regarding “predecessors in  
25 interest” are vague and ambiguous. Defendants are without knowledge or information to form  
26 a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the  
27 remaining allegations in this Paragraph of the Complaint.

28

Gordon & Rees, LLP  
275 Battery Street, Suite 2000  
San Francisco, CA 94111

## **Response to Allegations Regarding Jurisdiction and Venue**

8. Defendants are without knowledge or information to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding the amount in controversy, and, therefore, deny that the same. However, Defendants admit that Plaintiffs claim that the amount in controversy exceeds \$75,000, exclusive of interests and costs.

9. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' citizenship and the amount in controversy, and, therefore, deny the same. However, Defendants admit that Plaintiffs claim that the parties are diverse and that the amount in controversy exceeds \$75,000, exclusive of interests and costs.

10. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding the judicial district in which the asserted claims allegedly arose, and, therefore, deny the same. Defendants deny committing a tort in the States of Florida, South Carolina, and California, and deny the remaining allegations in this paragraph of the Complaint.

11. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants admit that they do business in the State of California. Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

## **Response to Allegations Regarding Interdistrict Assignment**

12. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac. And Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on September 6, 2005.

## **Response to Factual Allegations**

13. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' medical condition and whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

14. Defendants admit that Bextra® was expected to reach consumers without substantial change from the time of sale. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants deny the remaining allegations this paragraph of the Complaint.

15. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants deny remaining the allegations in this paragraph of the Complaint.

16. Plaintiffs' Complaint omits Paragraph 16.

17. Plaintiffs' Complaint omits Paragraph 17.

18. Defendants admit that Bextra® is in a class of drugs that is, at times, referred to as non-steroidal anti-inflammatory drugs (“NSAIDS”). Defendants state that Bextra® was and is safe

1 and effective when used in accordance with its FDA-approved prescribing information.  
2 Defendants state that the potential effects of Bextra® were and are adequately described in its  
3 FDA-approved prescribing information, which was at all times adequate and comported with  
4 applicable standards of care and law. Defendants deny the remaining allegations in this  
5 paragraph of the Complaint.

6 19. The allegations in this paragraph of the Complaint are not directed toward Defendants  
7 and, therefore, no response is required. To the extent a response is deemed required,  
8 Defendants state that Plaintiffs fail to provide the proper context for the allegations in this  
9 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to  
10 form a belief as to the truth of such allegations and, therefore, deny the same.

11 20. The allegations in this paragraph of the Complaint are not directed toward Defendants  
12 and, therefore, no response is required. To the extent a response is deemed required,  
13 Defendants state that Plaintiffs fail to provide the proper context for the allegations in this  
14 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to  
15 form a belief as to the truth of such allegations and, therefore, deny the same.

16 21. The allegations in this paragraph of the Complaint are not directed toward Defendants  
17 and, therefore, no response is required. To the extent a response is deemed required,  
18 Defendants state that Plaintiffs fail to provide the proper context for the allegations in this  
19 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to  
20 form a belief as to the truth of such allegations and, therefore, deny the same.

21 22. The allegations in this paragraph of the Complaint are not directed toward Defendants  
22 and, therefore, no response is required. To the extent a response is deemed required,  
23 Defendants state that Plaintiffs fail to provide the proper context for the allegations in this  
24 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to  
25 form a belief as to the truth of such allegations and, therefore, deny the same.

26 23. Plaintiffs fail to provide the proper context for the allegations in this paragraph of the  
27 Complaint. Defendants lack sufficient information or knowledge to form a belief as to the truth  
28 of such allegations and, therefore, deny the same.

Gordon & Rees, LLP  
275 Battery Street, Suite 2000  
San Francisco, CA 94111

1 24. Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are  
2 vague and ambiguous. Defendants are without knowledge or information to form a belief as to  
3 the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful  
4 conduct and deny the remaining allegations in this paragraph of the Complaint.

5 25. Plaintiffs do not allege having used Celebrex® in this Complaint. Nevertheless,  
6 Defendants admit that Celebrex® was launched in the United States in February 1999.  
7 Defendants state that Celebrex® was and is safe and effective when used in accordance with its  
8 FDA-approved prescribing information. Defendants admit that, during certain periods of time,  
9 Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be  
10 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance  
11 with their approval by the FDA. Defendants admit that, during certain periods of time,  
12 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-  
13 promoted and distributed Celebrex® in the United States to be prescribed by healthcare  
14 providers who are by law authorized to prescribe drugs in accordance with their approval by the  
15 FDA. The allegations in this paragraph of the Complaint regarding Merck and Vioxx® are not  
16 directed toward Defendants and, therefore, no response is required. To the extent a response is  
17 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the  
18 allegations in this paragraph of the Complaint regarding Merck and Vioxx®. Defendants  
19 therefore lack sufficient information or knowledge to form a belief as to the truth of such  
20 allegations and, therefore, deny the same. Defendants deny the remaining allegations in this  
21 paragraph of the Complaint.

22 26. Defendants admit that the New Drug Application for Bextra® was filed with the FDA  
23 on January 15, 2001. Defendants admit, as indicated in the package insert approved by the  
24 FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis  
25 and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea.  
26 Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and  
27 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of  
28 such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in

Gordon & Rees, LLP  
275 Battery Street, Suite 2000  
San Francisco, CA 94111

1 this paragraph of the Complaint.

2 27. Defendants admit that Bextra® was approved by the FDA on November 16, 2001.  
3 Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is  
4 indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid  
5 arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining  
6 allegations in this paragraph of the Complaint.

7 28. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®  
8 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult  
9 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny  
10 the remaining allegations in this paragraph of the Complaint.

11 29. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®  
12 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult  
13 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state  
14 that Bextra® was and is safe and effective when used in accordance with its FDA-approved  
15 prescribing information. Defendants state that the potential effects of Bextra® were and are  
16 adequately described in its FDA-approved prescribing information, which at all times was  
17 adequate and comported with applicable standards of care and law. Defendants deny the  
18 remaining allegations in this paragraph of the Complaint.

19 30. Defendants state that Bextra® was and is safe and effective when used in accordance  
20 with its FDA-approved prescribing information. Defendants state that the potential effects of  
21 Bextra® were and are adequately described in its FDA-approved prescribing information,  
22 which at all times was adequate and comported with applicable standards of care and law.  
23 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
24 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law  
25 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit  
26 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which  
27 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be  
28 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance

Gordon & Rees, LLP  
275 Battery Street, Suite 2000  
San Francisco, CA 94111

1 with their approval by the FDA. Defendants state that Plaintiffs' allegations regarding  
2 "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or  
3 information to form a belief as to the truth of such allegations, and, therefore, deny the same.  
4 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
5 the Complaint.

6 31. Defendants state that the referenced article speaks for itself and respectfully refer the  
7 Court to the article for its actual language and text. Any attempt to characterize the article is  
8 denied. Defendants state that Bextra® was and is safe and effective when used in accordance  
9 with its FDA-approved prescribing information. Defendants deny the remaining allegations in  
10 this paragraph of the Complaint.

11 32. The allegations in this paragraph of the Complaint are not directed towards Defendants  
12 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants  
13 state that the referenced article speaks for itself and respectfully refer the Court to the article for  
14 its actual language and text. Any attempt to characterize the article is denied. Defendants deny  
15 the remaining allegations in this paragraph of the Complaint.

16 33. Defendants admit that the New Drug Application for Bextra® was filed with the FDA  
17 on January 15, 2001. Defendants admit that Bextra® was approved by the FDA, on November  
18 16, 2001. Defendants deny any wrongful conduct and the remaining allegations in this  
19 paragraph of the Complaint.

20 34. Defendants state that Bextra® was and is safe and effective when used in accordance  
21 with its FDA-approved prescribing information. Defendants state that the potential effects of  
22 Bextra® were and are adequately described in its FDA-approved prescribing information,  
23 which at all times was adequate and comported with applicable standards of care and law.  
24 Defendants deny the allegations in this paragraph of the Complaint.

25 35. Defendants state that the referenced FDA Talk Paper for Bextra® speaks for itself and  
26 respectfully refer the Court to the Talk Paper for its actual language and text. Any attempt to  
27 characterize the Talk Paper is denied. Defendants deny the remaining allegations in this  
28 paragraph of the Complaint.

Gordon & Rees, LLP  
275 Battery Street, Suite 2000  
San Francisco, CA 94111

1 36. Defendants state that the referenced article speaks for itself and respectfully refer the  
2 Court to the article for its actual language and text. Any attempt to characterize the article is  
3 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

4 37. Plaintiffs fail to provide the proper context for the allegations concerning the “post-drug  
5 approval meta-analysis study” in this paragraph of the Complaint. Defendants are without  
6 sufficient information to confirm or deny such allegations and, therefore, deny the same.  
7 Defendants state that the referenced study speaks for itself and respectfully refer the Court to  
8 the study for its actual language and text. Any attempt to characterize the study is denied.  
9 Defendants deny the remaining allegations in this paragraph of the Complaint.

10 38. The allegations in this paragraph of the Complaint are not directed towards Defendants  
11 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants  
12 state that the referenced article speaks for itself and respectfully refer the Court to the article for  
13 its actual language and text. Any attempt to characterize the article is denied. Defendants deny  
14 the remaining allegations in this paragraph of the Complaint.

15 39. The allegations in this paragraph of the Complaint are not directed towards Defendants  
16 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants  
17 admit that a Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk  
18 Management Advisory Committee was held on February 16-18, 2005. Defendants state that the  
19 referenced testimony speaks for itself and respectfully refer the Court to the testimony for its  
20 actual language and text. Any attempt to characterize the testimony is denied. Defendants  
21 deny the remaining allegations in this paragraph of the Complaint.

22 40. Defendants state that Bextra® was and is safe and effective when used in accordance  
23 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and  
24 deny the remaining allegations in this paragraph of the Complaint.

25 41. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself  
26 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language  
27 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.  
28 Defendants deny the remaining allegations in this paragraph of the Complaint.

Gordon & Rees, LLP  
275 Battery Street, Suite 2000  
San Francisco, CA 94111

1 42. Defendants state that Plaintiffs fail to provide the proper context for the allegations in  
2 this paragraph of the Complaint. Defendants therefore lack sufficient information or  
3 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

4 43. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself  
5 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language  
6 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.  
7 Defendants deny the remaining allegations in this paragraph of the Complaint.

8 44. Defendants state that Bextra® was and is safe and effective when used in accordance  
9 with its FDA-approved prescribing information. Defendants deny the allegations in this  
10 paragraph of the Complaint.

11 45. Defendants state that the referenced article speaks for itself and respectfully refer the  
12 Court to the article for its actual language and text. Any attempt to characterize the article is  
13 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this  
14 paragraph of the Complaint.

15 46. The allegations in this paragraph of the Complaint are not directed towards Defendants  
16 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants  
17 state that the referenced article speaks for itself and respectfully refer the Court to the article for  
18 its actual language and text. Any attempt to characterize the article is denied. Defendants deny  
19 the remaining allegations in this paragraph of the Complaint.

20 47. Defendants state that Bextra® was and is safe and effective when used in accordance  
21 with its FDA-approved prescribing information. Defendants state that the potential effects of  
22 Bextra® were and are adequately described in its FDA-approved prescribing information,  
23 which was at all times adequate and comported with applicable standards of care and law.  
24 Defendants deny the allegations in this paragraph of the Complaint.

25 48. Defendants state that Bextra® was and is safe and effective when used in accordance  
26 with its FDA-approved prescribing information. Defendants state that the potential effects of  
27 Bextra® were and are adequately described in its FDA-approved prescribing information,  
28 which was at all times adequate and comported with applicable standards of care and law.

Gordon & Rees, LLP  
275 Battery Street, Suite 2000  
San Francisco, CA 94111

1 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining  
2 allegations in this paragraph of the Complaint.

3 49. Defendants state that Bextra® was and is safe and effective when used in accordance  
4 with its FDA-approved prescribing information. Defendants state that the potential effects of  
5 Bextra® were and are adequately described in its FDA-approved prescribing information,  
6 which was at all times adequate and comported with applicable standards of care and law.  
7 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
8 the Complaint.

9 50. Defendants deny the allegations in this paragraph of the Complaint.

10 51. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
11 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are  
12 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
13 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,  
14 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to  
15 be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
16 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and  
17 effective when used in accordance with its FDA-approved prescribing information. Defendants  
18 state that the potential effects of Bextra® were and are adequately described in its FDA-  
19 approved prescribing information, which was at all times adequate and comported with  
20 applicable standards of care and law. Defendants are without knowledge or information  
21 sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used  
22 Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct and deny the  
23 allegations in this paragraph of the Complaint.

24 52. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
25 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are  
26 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
27 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,  
28 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to

Gordon & Rees, LLP  
275 Battery Street, Suite 2000  
San Francisco, CA 94111

1 be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
2 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and  
3 effective when used in accordance with its FDA-approved prescribing information. Defendants  
4 state that the potential effects of Bextra® were and are adequately described in its FDA-  
5 approved prescribing information, which was at all times adequate and comported with  
6 applicable standards of care and law. Defendants deny the remaining allegations in this  
7 paragraph of the Complaint.

8 53. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
9 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are  
10 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
11 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,  
12 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to  
13 be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
14 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and  
15 effective when used in accordance with its FDA-approved prescribing information. Defendants  
16 state that the potential effects of Bextra® were and are adequately described in its FDA-  
17 approved prescribing information, which was at all times adequate and comported with  
18 applicable standards of care and law. Defendants admit, as indicated in the package insert  
19 approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms  
20 of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary  
21 dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

22 54. Defendants state that Bextra® was and is safe and effective when used in accordance  
23 with its FDA-approved prescribing information. Defendants state that the potential effects of  
24 Bextra® were and are adequately described in its FDA-approved prescribing information,  
25 which at all times was adequate and comported with applicable standards of care and law.  
26 Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and  
27 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of  
28 such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny

Gordon & Rees, LLP  
275 Battery Street, Suite 2000  
San Francisco, CA 94111

1 that Bextra® is defective, and deny the allegations in this paragraph of the Complaint.

2 55. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
3 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are  
4 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
5 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,  
6 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to  
7 be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
8 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and  
9 effective when used in accordance with its FDA-approved prescribing information. Defendants  
10 state that the potential effects of Bextra® were and are adequately described in its FDA-  
11 approved prescribing information, which was at all times adequate and comported with  
12 applicable standards of care and law. Defendants deny the remaining allegations in this  
13 paragraph of the Complaint.

14 56. Defendants state that Bextra® was and is safe and effective when used in accordance  
15 with its FDA-approved prescribing information. Defendants state that the potential effects of  
16 Bextra® were and are adequately described in its FDA-approved prescribing information,  
17 which at all times was adequate and comported with applicable standards of care and law.  
18 Defendants deny the remaining allegations in this paragraph of the Complaint.

19 57. Defendants state that Bextra® was and is safe and effective when used in accordance  
20 with its FDA-approved prescribing information. Defendants state that the potential effects of  
21 Bextra® were and are adequately described in its FDA-approved prescribing information,  
22 which was at all times adequate and comported with applicable standards of care and law.  
23 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
24 the Complaint.

25 58. Defendants state that Bextra® was and is safe and effective when used in accordance  
26 with its FDA-approved prescribing information. Defendants state that the potential effects of  
27 Bextra® were and are adequately described in its FDA-approved prescribing information,  
28 which was at all times adequate and comported with applicable standards of care and law.

Gordon & Rees, LLP  
275 Battery Street, Suite 2000  
San Francisco, CA 94111

1 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
2 the Complaint.

3 59. Defendants deny the allegations in this paragraph of the Complaint.

4 60. Defendants admit that the sale of Bextra® was voluntarily suspended in the U.S. market  
5 as of April 7, 2005. Defendants deny any wrongful conduct and deny the remaining allegations  
6 contained in this paragraph of the Complaint.

7 61. Defendants state that Bextra® was and is safe and effective when used in accordance  
8 with its FDA-approved prescribing information. Defendants state that the potential effects of  
9 Bextra® were and are adequately described in its FDA-approved prescribing information,  
10 which was at all times adequate and comported with applicable standards of care and law.  
11 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining  
12 allegations in this paragraph of the Complaint.

13 62. Defendants state that Bextra® was and is safe and effective when used in accordance  
14 with its FDA-approved prescribing information. Defendants state that the potential effects of  
15 Bextra® were and are adequately described in its FDA-approved prescribing information,  
16 which was at all times adequate and comported with applicable standards of care and law.  
17 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
18 the Complaint.

19 63. Defendants deny any wrongful conduct and deny the remaining allegations in this  
20 paragraph of the Complaint.

21 64. Defendants state that Bextra® was and is safe and effective when used in accordance  
22 with its FDA-approved prescribing information. Defendants state that the potential effects of  
23 Bextra® were and are adequately described in its FDA-approved prescribing information,  
24 which was at all times adequate and comported with applicable standards of care and law.  
25 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
26 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law  
27 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit  
28 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which

Gordon & Rees, LLP  
275 Battery Street, Suite 2000  
San Francisco, CA 94111

1 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be  
2 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance  
3 with their approval by the FDA. Defendants deny any wrongful conduct and deny the  
4 remaining allegations in this paragraph of the Complaint.

5 65. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
6 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are  
7 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
8 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,  
9 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to  
10 be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
11 accordance with their approval by the FDA. Defendants deny the remaining allegations in this  
12 paragraph of the Complaint.

13 66. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
14 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are  
15 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
16 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,  
17 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to  
18 be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
19 accordance with their approval by the FDA. Defendants admit, as indicated in the package  
20 insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and  
21 symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of  
22 primary dysmenorrhea. Defendants deny any wrongful conduct and deny the remaining  
23 allegations in this paragraph of the Complaint.

24 67. Defendants state that Bextra® was and is safe and effective when used in accordance  
25 with its FDA-approved prescribing information. Defendants state that the potential effects of  
26 Bextra® were and are adequately described in its FDA-approved prescribing information,  
27 which was at all times adequate and comported with applicable standards of care and law.  
28 Defendants are without knowledge or information sufficient to form a belief as to the truth of

Gordon & Rees, LLP  
275 Battery Street, Suite 2000  
San Francisco, CA 94111

1 the allegations regarding and whether Plaintiffs used Bextra® and, therefore, deny the same.  
2 Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra®  
3 caused Plaintiffs injury or damages, and deny the remaining allegations in this paragraph of the  
4 Complaint.

5 68. Defendants state that Bextra® was and is safe and effective when used in accordance  
6 with its FDA-approved prescribing information. Defendants state that the potential effects of  
7 Bextra® were and are adequately described in its FDA-approved prescribing information,  
8 which was at all times adequate and comported with applicable standards of care and law.  
9 Defendants are without knowledge or information sufficient to form a belief as to the truth of  
10 the allegations regarding and whether Plaintiffs used Bextra® and, therefore, deny the same.  
11 Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and  
12 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of  
13 such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny  
14 that Bextra® is defective, deny that Bextra® caused Plaintiffs injury or damages, and deny the  
15 remaining allegations in this paragraph of the Complaint.

16 **Response to First Cause of Action: Negligence**

17 69. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
18 Complaint as if fully set forth herein.

19 70. Defendants state that this paragraph of the Complaint contains legal contentions to  
20 which no response is deemed required. To the extent a response is deemed required,  
21 Defendants admit that they had duties as are imposed by law but deny having breached such  
22 duties. Defendants state that the potential effects of Bextra® were and are adequately described  
23 in its FDA-approved prescribing information, which was at all times adequate and comported  
24 with applicable standards of care and law. Defendants state that Bextra® was and is safe and  
25 effective when used in accordance with its FDA-approved prescribing information. Defendants  
26 deny the remaining allegations in this paragraph of the Complaint.

27 71. Defendants state that this paragraph of the Complaint contains legal contentions to  
28 which no response is deemed required. To the extent a response is deemed required,

1 Defendants admit that they had duties as are imposed by law but deny having breached such  
2 duties. Defendants state that Bextra® was and is safe and effective when used in accordance  
3 with its FDA-approved prescribing information. Defendants deny the remaining allegations in  
4 this paragraph of the Complaint.

5 72. Defendants state that this paragraph of the Complaint contains legal contentions to  
6 which no response is required. To the extent that a response is deemed required, Defendants  
7 admit that they had duties as are imposed by law but deny having breached such duties.  
8 Defendants state that Bextra® was and is safe and effective when used in accordance with its  
9 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®  
10 were and are adequately described in its FDA-approved prescribing information, which was at  
11 all times adequate and comported with applicable standards of care and law. Defendants deny  
12 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint,  
13 including all subparts.

14 73. Defendants state that Bextra® was and is safe and effective when used in accordance  
15 with its FDA-approved prescribing information. Defendants state that the potential effects of  
16 Bextra® were and are adequately described in its FDA-approved prescribing information,  
17 which was at all times adequate and comported with applicable standards of care and law.  
18 Defendants are without knowledge or information sufficient to form a belief as to the truth of  
19 the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same.  
20 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
21 the Complaint.

22 74. Defendants state that Bextra® was and is safe and effective when used in accordance  
23 with its FDA-approved prescribing information. Defendants state that the potential effects of  
24 Bextra® were and are adequately described in its FDA-approved prescribing information,  
25 which was at all times adequate and comported with applicable standards of care and law.  
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
27 the Complaint.

28 75. Defendants state that Bextra® was and is safe and effective when used in accordance

1 with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny  
2 that Bextra® caused Plaintiffs injury or damages, and deny the remaining allegations in this  
3 paragraph of the Complaint.

4 76. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
5 damages, and deny the remaining allegations in this paragraph of the Complaint.

6 77. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
7 damages and deny the remaining allegations in this paragraph of the Complaint.

8 78. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
9 damages, and deny the remaining allegations in this paragraph of the Complaint.

10 **Response to Second Cause of Action: Strict Liability**

11 79. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
12 Complaint as if fully set forth herein.

13 80. Defendants are without knowledge or information sufficient to form a belief as to the  
14 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
15 same. Defendants admit that Bextra® was expected to reach consumers without substantial  
16 change in the condition from the time of sale. Defendants state that Bextra® was and is safe  
17 and effective when used in accordance with its FDA-approved prescribing information.  
18 Defendants state that the potential effects of Bextra® were and are adequately described in its  
19 FDA-approved prescribing information, which was at all times adequate and comported with  
20 applicable standards of care and law. Defendants admit that, during certain periods of time,  
21 Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed  
22 by healthcare providers who are by law authorized to prescribe drugs in accordance with their  
23 approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was  
24 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and  
25 distributed Bextra® in the United States to be prescribed by healthcare providers who are by  
26 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
27 deny the remaining allegations in this paragraph of the Complaint.

28 81. Defendants state that Bextra® was and is safe and effective when used in accordance

1 with its FDA-approved prescribing information. Defendants state that the potential effects of  
2 Bextra® were and are adequately described in its FDA-approved prescribing information,  
3 which was at all times adequate and comported with applicable standards of care and law.  
4 Defendants deny the allegations in this paragraph of the Complaint.

5 82. Defendants state that Bextra® was and is safe and effective when used in accordance  
6 with its FDA-approved prescribing information. Defendants state that the potential effects of  
7 Bextra® were and are adequately described in its FDA-approved prescribing information,  
8 which was at all times adequate and comported with applicable standards of care and law.  
9 Defendants deny that Bextra® is defective or unreasonably dangerous, and deny the remaining  
10 allegations in this paragraph of the Complaint.

11 83. Defendants state that this paragraph of the Complaint contains legal contentions to  
12 which no response is deemed required. To the extent a response is deemed required,  
13 Defendants state that Bextra® was and is safe and effective when used in accordance with its  
14 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®  
15 were and are adequately described in its FDA-approved prescribing information, which was at  
16 all times adequate and comported with applicable standards of care and law. Defendants deny  
17 that Bextra® is unreasonably dangerous, and deny the remaining allegations in this paragraph  
18 of the Complaint, including all subparts.

19 84. Defendants state that this paragraph of the Complaint contains legal contentions to  
20 which no response is deemed required. To the extent a response is deemed required,  
21 Defendants state that Bextra® was and is safe and effective when used in accordance with its  
22 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®  
23 were and are adequately described in its FDA-approved prescribing information, which was at  
24 all times adequate and comported with applicable standards of care and law. Defendants deny  
25 any wrongful conduct, deny that Bextra® is unreasonably dangerous, and deny the remaining  
26 allegations in this paragraph of the Complaint.

27 85. Defendants state that Bextra® was and is safe and effective when used in accordance  
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

Gordon & Rees, LLP  
275 Battery Street, Suite 2000  
San Francisco, CA 94111

1 Bextra® were and are adequately described in its FDA-approved prescribing information,  
2 which was at all times adequate and comported with applicable standards of care and law.  
3 Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra®  
4 caused Plaintiffs injury or damages, and deny the remaining allegations in this paragraph of the  
5 Complaint.

6 86. Defendants state that Bextra® was and is safe and effective when used in accordance  
7 with its FDA-approved prescribing information. Defendants state that the potential effects of  
8 Bextra® were and are adequately described in its FDA-approved prescribing information,  
9 which was at all times adequate and comported with applicable standards of care and law.  
10 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining  
11 allegations in this paragraph of the Complaint.

12 87. Defendants are without knowledge or information sufficient to form a belief as to the  
13 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
14 same. Defendants state that Bextra® was and is safe and effective when used in accordance  
15 with its FDA-approved prescribing information. Defendants state that the potential effects of  
16 Bextra® were and are adequately described in its FDA-approved prescribing information,  
17 which was at all times adequate and comported with applicable standards of care and law.  
18 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
19 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law  
20 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit  
21 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which  
22 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be  
23 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance  
24 with their approval by the FDA. Defendants deny any wrongful conduct, deny that Bextra® is  
25 defective, deny that Bextra® caused Plaintiffs injury or damages, and deny the remaining  
26 allegations in this paragraph of the Complaint.

27 88. Defendants state that Bextra® was and is safe and effective when used in accordance  
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

1 Bextra® were and are adequately described in its FDA-approved prescribing information,  
2 which was at all times adequate and comported with applicable standards of care and law.  
3 Defendants deny the remaining allegations in this paragraph of the Complaint.

4 89. Defendants are without knowledge or information sufficient to form a belief as to the  
5 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
6 same. Defendants state that Bextra® was and is safe and effective when used in accordance  
7 with its FDA-approved prescribing information. Defendants state that the potential effects of  
8 Bextra® were and are adequately described in its FDA-approved prescribing information,  
9 which was at all times adequate and comported with applicable standards of care and law.  
10 Defendants deny the remaining allegations in this paragraph of the Complaint.

11 90. Defendants state that Bextra® was and is safe and effective when used in accordance  
12 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and  
13 deny the remaining allegations in this paragraph of the Complaint.

14 91. Defendants are without knowledge or information sufficient to form a belief as to the  
15 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
16 same. Defendants state that Bextra® was and is safe and effective when used in accordance  
17 with its FDA-approved prescribing information. Defendants state that the potential effects of  
18 Bextra® were and are adequately described in its FDA-approved prescribing information,  
19 which was at all times adequate and comported with applicable standards of care and law.  
20 Defendants deny that Bextra® is defective and deny the remaining allegations in this paragraph  
21 of the Complaint.

22 92. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
23 damages, and deny the remaining allegations in this paragraph of the Complaint.

24 93. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
25 damages, and deny the remaining allegations in this paragraph of the Complaint.

26 94. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
27 damages, and deny the remaining allegations in this paragraph of the Complaint.

28

Gordon & Rees, LLP  
275 Battery Street, Suite 2000  
San Francisco, CA 94111

## **Response to Third Cause of Action: Breach of Express Warranty**

95. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

96. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

97. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint, including all subparts.

98. Defendants deny the allegations in this paragraph of the Complaint.

99. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

100. Defendants state that Bextra® was and is safe and effective when used in accordance

1 with its FDA-approved prescribing information. Defendants state that the potential effects of  
 2 Bextra® were and are adequately described in its FDA-approved prescribing information,  
 3 which was at all times adequate and comported with applicable standards of care and law.  
 4 Defendants admit that they provided FDA-approved prescribing information regarding  
 5 Bextra®. Defendants deny any wrongful conduct the remaining allegations in this paragraph of  
 6 the Complaint.

7 101. Defendants are without knowledge or information sufficient to form a belief as to the  
 8 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
 9 same. Defendants admit that they provided FDA-approved prescribing information regarding  
 10 Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

11 102. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
 12 damages, and deny the remaining allegations in this paragraph of the Complaint.

13 103. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
 14 damages, and deny the remaining allegations in this paragraph of the Complaint.

15 104. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
 16 damages, and deny the remaining allegations in this paragraph of the Complaint.

17 **Response to Fourth Cause of Action: Breach of Implied Warranty**

18 105. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
 19 Complaint as if fully set forth herein.

20 106. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
 21 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are  
 22 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
 23 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,  
 24 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to  
 25 be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
 26 accordance with their approval by the FDA. Defendants deny the remaining allegations in this  
 27 paragraph of the Complaint.

28 107. Defendants admit that they provided FDA-approved prescribing information regarding

Gordon & Rees, LLP  
 275 Battery Street, Suite 2000  
 San Francisco, CA 94111

1 Bextra®. Defendants admit, as indicated in the package insert approved by the FDA, that  
2 Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult  
3 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state  
4 that Bextra® was and is safe and effective when used in accordance with its FDA-approved  
5 prescribing information. Defendants deny the remaining allegations in this paragraph of the  
6 Complaint.

7 108. Defendants are without knowledge or information sufficient to form a belief as to the  
8 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
9 same. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®  
10 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult  
11 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny  
12 the remaining allegations in this paragraph of the Complaint.

13 109. Defendants are without knowledge or information sufficient to form a belief as to the  
14 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
15 same. Defendants state that Bextra® was and is safe and effective when used in accordance  
16 with its FDA-approved prescribing information. Defendants deny the remaining allegations in  
17 this paragraph of the Complaint.

18 110. Defendants are without knowledge or information sufficient to form a belief as to the  
19 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
20 same. Defendants state that Bextra® was expected to reach consumers without substantial  
21 change in the condition from the time of sale. Defendants deny the remaining allegations in  
22 this paragraph of the Complaint.

23 111. Defendants are without knowledge or information sufficient to form a belief as to the  
24 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
25 same. Defendants state that Bextra® was and is safe and effective when used in accordance  
26 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and  
27 deny the remaining allegations in this paragraph of the Complaint.

28 112. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or

Gordon & Rees, LLP  
275 Battery Street, Suite 2000  
San Francisco, CA 94111

1 damages, and deny the remaining allegations in this paragraph of the Complaint.

2 113. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
3 damages, and deny the remaining allegations in this paragraph of the Complaint.

4 114. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
5 damages, and deny the remaining allegations in this paragraph of the Complaint.

6 **Response to Fifth Cause of Action: Fraudulent Misrepresentation & Concealment**

7 115. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
8 Complaint as if fully set forth herein.

9 116. Defendants state that this paragraph of the Complaint contains legal contentions to  
10 which no response is deemed required. To the extent a response is deemed required,  
11 Defendants admit that they had duties as are imposed by law but deny having breached such  
12 duties. Defendants state that Bextra® was and is safe and effective when used in accordance  
13 with its FDA-approved prescribing information. Defendants state that the potential effects of  
14 Bextra® were and are adequately described in its FDA-approved prescribing information,  
15 which was at all times adequate and comported with applicable standards of care and law.  
16 Defendants deny the remaining allegations in this paragraph of the Complaint.

17 117. Defendants state that Bextra® was and is safe and effective when used in accordance  
18 with its FDA-approved prescribing information. Defendants state that the potential effects of  
19 Bextra® were and are adequately described in its FDA-approved prescribing information,  
20 which was at all times adequate and comported with applicable standards of care and law.  
21 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
22 the Complaint, including all subparts.

23 118. Defendants state that Bextra® was and is safe and effective when used in accordance  
24 with its FDA-approved prescribing information. Defendants state that the potential effects of  
25 Bextra® were and are adequately described in its FDA-approved prescribing information,  
26 which was at all times adequate and comported with applicable standards of care and law.  
27 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
28 the Complaint.

Gordon & Rees, LLP  
275 Battery Street, Suite 2000  
San Francisco, CA 94111

1 119. Defendants state that Bextra® was and is safe and effective when used in accordance  
2 with its FDA-approved prescribing information. Defendants state that the potential effects of  
3 Bextra® were and are adequately described in its FDA-approved prescribing information,  
4 which was at all times adequate and comported with applicable standards of care and law.  
5 Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably  
6 dangerous, and deny the remaining allegations in this paragraph of the Complaint.

7 120. Defendants state that Bextra® was and is safe and effective when used in accordance  
8 with its FDA-approved prescribing information. Defendants state that the potential effects of  
9 Bextra® were and are adequately described in its FDA-approved prescribing information,  
10 which was at all times adequate and comported with applicable standards of care and law.  
11 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
12 the Complaint.

13 121. Defendants deny any wrongful conduct and deny the remaining allegations in this  
14 paragraph of the Complaint.

15 122. Defendants are without knowledge or information sufficient to form a belief as to the  
16 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
17 same. Defendants deny any wrongful conduct and deny the remaining allegations in this  
18 paragraph of the Complaint.

19 123. Defendants are without knowledge or information sufficient to form a belief as to the  
20 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
21 same. Defendants deny any wrongful conduct and deny the remaining allegations in this  
22 paragraph of the Complaint.

23 124. Defendants are without knowledge or information sufficient to form a belief as to the  
24 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
25 same. Defendants deny any wrongful conduct and deny the remaining allegations in this  
26 paragraph of the Complaint.

27 125. Defendants deny any wrongful conduct and deny the remaining allegations in this  
28 paragraph of the Complaint.

Gordon & Rees, LLP  
275 Battery Street, Suite 2000  
San Francisco, CA 94111

1 126. Defendants are without knowledge or information sufficient to form a belief as to the  
2 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
3 same. Defendants state that Bextra® was and is safe and effective when used in accordance  
4 with its FDA-approved prescribing information. Defendants state that the potential effects of  
5 Bextra® were and are adequately described in its FDA-approved prescribing information,  
6 which was at all times adequate and comported with applicable standards of care and law.  
7 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
8 the Complaint.

9 127. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
10 damages, and deny the remaining allegations in this paragraph of the Complaint.

11 128. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
12 damages, and deny the remaining allegations in this paragraph of the Complaint.

13 129. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
14 damages, and deny the remaining allegations in this paragraph of the Complaint.

15 **Response to Sixth Cause of Action: Unjust Enrichment**

16 130. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
17 Complaint as if fully set forth herein.

18 131. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
19 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are  
20 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
21 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,  
22 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to  
23 be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
24 accordance with their approval by the FDA. Defendants deny the remaining allegations in this  
25 paragraph of the Complaint.

26 132. Defendants are without knowledge or information sufficient to form a belief as to the  
27 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
28 same. Defendants deny the remaining allegations in this paragraph of the Complaint.

Gordon & Rees, LLP  
275 Battery Street, Suite 2000  
San Francisco, CA 94111

1 133. Defendants are without knowledge or information sufficient to form a belief as to the  
 2 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
 3 same. Defendants deny the remaining allegations in this paragraph of the Complaint.

4 134. Defendants are without knowledge or information sufficient to form a belief as to the  
 5 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
 6 same. Defendants state that Bextra® was and is safe and effective when used in accordance  
 7 with its FDA-approved prescribing information. Defendants deny the remaining allegations in  
 8 this paragraph of the Complaint.

9 135. Defendants are without knowledge or information sufficient to form a belief as to the  
 10 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
 11 same. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
 12 damages, and deny the remaining allegations in this paragraph of the Complaint.

13 136. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
 14 damages, and deny the remaining allegations in this paragraph of the Complaint.

15 **Response to Prayer for Relief**

16 Answering the unnumbered paragraph of the Complaint headed "Prayer for Relief,"  
 17 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damages,  
 18 and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

19 **III.**

20 **GENERAL DENIAL**

21 Defendants deny all allegations and/or legal conclusions set forth in Plaintiffs'  
 22 Complaint that have not been previously admitted, denied, or explained.

23 **IV.**

24 **AFFIRMATIVE DEFENSES**

25 Defendants reserve the right to rely upon any of the following or additional defenses to  
 26 claims asserted by Plaintiffs to the extent that such defenses are supported by information  
 27 developed through discovery or evidence at trial. Defendants affirmatively show that:

Gordon & Rees, LLP  
 275 Battery Street, Suite 2000  
 San Francisco, CA 94111

**Gordon & Rees, LLP**  
2275 Battery Street, Suite 2000  
San Francisco CA 94111

## First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

## **Second Defense**

2. Bextra® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants' labeling and warning of Bextra® was at all times in compliance with applicable federal law. Plaintiffs' causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

### **Third Defense**

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

## **Fourth Defense**

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Bextra® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

## Fifth Defense

5. Plaintiffs' action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pleaded in full bar of any liability as to Defendants.

## Sixth Defense

6. Plaintiffs' action is barred by the statute of repose.

## **Seventh Defense**

7. If Plaintiffs sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the negligence or fault of the Plaintiffs and Plaintiffs' damages, if any, are barred or reduced by the doctrines of comparative fault and contributory negligence and by the failure to mitigate damages.

Gordon & Rees, LLP  
 275 Battery Street, Suite 2000  
 San Francisco, CA 94111

**Eighth Defense**

8. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

**Ninth Defense**

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

**Tenth Defense**

10. Any injuries or expenses incurred by Plaintiffs were not caused by Bextra®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

**Eleventh Defense**

11. Defendants affirmatively deny that they violated any duty owed to Plaintiffs.

**Twelfth Defense**

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a "learned intermediary" in determining the use of the product. Bextra® is a prescription medical product, available only on the order of a licensed physician. Bextra® provided an adequate warning to Plaintiffs' treating and prescribing physicians.

**Thirteenth Defense**

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

**Fourteenth Defense**

14. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Bextra® at the time of the

1 occurrence of the injuries alleged by Plaintiffs were legally adequate for its approved usages.

2 **Fifteenth Defense**

3 15. Plaintiffs' causes of action are barred in whole or in part by the lack of a defect as the  
4 Bextra® allegedly ingested by Plaintiffs was prepared in accordance with the applicable  
5 standard of care.

6 **Sixteenth Defense**

7 16. If Plaintiffs sustained any injuries or incurred any losses or damages as alleged in the  
8 Complaint, the same were caused by the unforeseeable alteration, change, improper handling,  
9 abnormal use, or other unforeseeable misuse of Bextra® by persons other than Defendants or  
10 persons acting on its behalf after the product left the control of Defendants.

11 **Seventeenth Defense**

12 17. Plaintiffs' alleged damages were not caused by any failure to warn on the part of  
13 Defendants.

14 **Eighteenth Defense**

15 18. Plaintiffs' alleged injuries/damages, if any, were the result of preexisting or subsequent  
16 conditions unrelated to Bextra®.

17 **Nineteenth Defense**

18 19. Plaintiffs knew or should have known of any risk associated with Bextra®; therefore,  
19 the doctrine of assumption of the risk bars or diminishes any recovery.

20 **Twentieth Defense**

21 20. Plaintiffs are barred from recovering against Defendants because Plaintiffs' claims are  
22 preempted in accordance with the Supremacy Clause of the United States Constitution and by  
23 the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

24 **Twenty-first Defense**

25 21. Plaintiffs' claims are barred in whole or in part under the applicable state law because  
26 the subject pharmaceutical product at issue was subject to and received pre-market approval by  
27 the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

## Twenty-second Defense

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiffs' Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiffs' causes of action are preempted.

## **Twenty-third Defense**

23. Plaintiffs' claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

## **Twenty-fourth Defense**

24. Plaintiffs' claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

## **Twenty-fifth Defense**

25. Plaintiffs' claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

## Twenty-sixth Defense

26. Plaintiffs' claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

## Twenty-seventh Defense

27. Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

## Twenty-eighth Defense

28. Plaintiffs' claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

## Twenty-ninth Defense

29. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs have failed to plead facts sufficient under the law to justify an award of punitive damages.

## Thirtieth Defense

30. The imposition of punitive damages in this case would violate Defendants' rights to procedural due process under the Fourteenth Amendment of the United States Constitution, the Constitutions of the States of Florida, South Carolina, and California, and would additionally violate Defendants' right to substantive due process under the Fourteenth Amendment of the United States Constitution.

## Thirty-first Defense

31. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

## **Thirty-second Defense**

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

### **Thirty-third Defense**

33. Plaintiffs' punitive damage claims are preempted by federal law.

## **Thirty-fourth Defense**

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

## **Thirty-fifth Defense**

35. Plaintiffs failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

## **Thirty-sixth Defense**

36. To the extent that Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

## Thirty-seventh Defense

37. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

## **Thirty-eighth Defense**

38. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution and the Constitutions of the States of Florida, South Carolina, and California. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiffs; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiffs and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), *TXO Production Corp. v. Alliance Resources*,

1 *Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State*  
2 *Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

3 **Thirty-ninth Defense**

4 39. The methods, standards, and techniques utilized with respect to the manufacture, design,  
5 and marketing of Bextra®, if any, used in this case, included adequate warnings and  
6 instructions with respect to the product's use in the package insert and other literature, and  
7 conformed to the generally recognized, reasonably available, and reliable state of the  
8 knowledge at the time the product was marketed.

9 **Fortieth Defense**

10 40. The claims asserted in the Complaint are barred because Bextra® was designed, tested,  
11 manufactured and labeled in accordance with the state-of-the-art industry standards existing at  
12 the time of the sale.

13 **Forty-first Defense**

14 41. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon  
15 information and belief, such injuries and losses were caused by the actions of persons not  
16 having real or apparent authority to take said actions on behalf of Defendants and over whom  
17 Defendants had no control and for whom Defendants may not be held accountable.

18 **Forty-second Defense**

19 42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra®  
20 was not unreasonably dangerous or defective, was suitable for the purpose for which it was  
21 intended, and was distributed with adequate and sufficient warnings.

22 **Forty-third Defense**

23 43. Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches,  
24 waiver, and/or estoppel.

25 **Forty-fourth Defense**

26 44. Plaintiffs' claims are barred because Plaintiffs' injuries, if any, were the result of the  
27 pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or  
28 illnesses, subsequent medical conditions or natural courses of conditions of Plaintiffs, and were

1 independent of or far removed from Defendants' conduct.

## **Forty-fifth Defense**

3 45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra®  
4 did not proximately cause injuries or damages to Plaintiffs.

## **Forty-sixth Defense**

6 46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs  
7 did not incur any ascertainable loss as a result of Defendants' conduct.

## **Forty-seventh Defense**

9 47. The claims asserted in the Complaint are barred, in whole or in part, because the  
10 manufacturing, labeling, packaging, and any advertising of the product complied with the  
11 applicable codes, standards and regulations established, adopted, promulgated or approved by  
12 any applicable regulatory body, including but not limited to the United States, any state, and  
13 any agency thereof.

## **Forty-eighth Defense**

15 48. The claims must be dismissed because Plaintiffs would have taken Bextra® even if the  
16 product labeling contained the information that Plaintiffs contend should have been provided.

## **Forty-ninth Defense**

18 49. The claims asserted in the Complaint are barred because the utility of Bextra®  
19 outweighed its risks.

## **Fiftieth Defense**

21 50. Plaintiffs' damages, if any, are barred or limited by the payments received from  
22 collateral sources.

## **Fifty-first Defense**

24 51. Defendants' liability, if any, can only be determined after the percentages of  
25 responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if  
26 any, are determined. Defendants seek an adjudication of the percentage of fault of the  
27 claimants and each and every other person whose fault could have contributed to the alleged  
28 injuries and damages, if any, of Plaintiffs.

**Gordon & Rees, LLP**  
**2275 Battery Street, Suite 2000**  
**San Francisco CA 94111**

## **Fifty-second Defense**

52. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

## **Fifty-third Defense**

6 53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is  
7 comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act  
8 (“FDCA”), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiffs’  
9 claims conflict with the FDCA, with the regulations promulgated by FDA to implement the  
10 FDCA, with the purposes and objectives of the FDCA and FDA’s implementing regulations,  
11 and with the specific determinations by FDA specifying the language that should be used in the  
12 labeling accompanying Bextra®. Accordingly, Plaintiffs’ claims are preempted by the  
13 Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the  
14 United States.

## **Fifty-fourth Defense**

54. Plaintiffs' misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

## Fifty-fifth Defense

19 55. Defendants state on information and belief that the Complaint and each purported cause  
20 of action contained therein is barred by the statutes of limitations contained in California Code  
21 of Civil Procedure §§ 335.1 and 338 and former § 340(3), such other statutes of limitation as  
22 may apply.

## **Fifty-sixth Defense**

24 56. Defendants state on information and belief that any injuries, losses, or damages suffered  
25 by Plaintiffs were proximately caused, in whole or in part, by the negligence or other actionable  
26 conduct of persons or entities other than Defendants. Therefore, Plaintiffs' recovery against  
27 Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

## **Fifty-seventh Defense**

57. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive damages is also barred under California Civil Code § 3294(b).

## **Fifty-eighth Defense**

58. Plaintiffs' fraud-based claims, if any, are not stated with particularity as required by Rule 1.120 of the Florida Rules of Civil Procedure.

## Fifty-ninth Defense

59. Plaintiffs' claims are barred because Bextra® was designed, manufactured, and marketed in accordance with the state of the art at the time of manufacture per section 768.1257, Florida Statutes.

## **Sixtieth Defense**

60. Bextra® is not defective or unreasonably dangerous, and Defendants are not liable because, at the time of sale or distribution of the Bextra® alleged to have been used by Plaintiffs, Defendants had complied with applicable regulations of the federal Food & Drug Administration and are entitled to application of section 768.1256, Florida Statutes.

## Sixty-first Defense

61. Plaintiffs' injuries and damages, if any, were proximately caused by the negligence or fault of Plaintiff, or persons or parties whose identities are unknown at this time, and such comparative negligence or fault is sufficient to proportionately reduce or bar Plaintiffs' recovery. Thus, Defendants are entitled to have their liability to the Plaintiffs, if any, reduced as a result of the negligence or fault of said persons or entities, pursuant to the provisions of section 768.81, Florida Statutes. To the extent any recovery is permitted in this case, pursuant to sections 768.31 and 768.81, Florida Statutes, judgment must be entered on the basis of Defendants' percentage of fault, taking into account the percentage of fault attributable to all other persons, whether or not a party hereto, and not on the basis of joint and several liability. The persons or entities referred to in this paragraph that are presently unknown to Defendants

1 will be identified in a timely manner consistent with *Nash v. Wells Fargo*, 678 So. 2d 1262  
 2 (Fla. 1996).

3 **Sixty-second Defense**

4 62. Plaintiffs fail to state a claim for violation of The Florida Deceptive and Unfair Trade  
 5 Practices Act (“FDUTPA”).

6 **Sixty-third Defense**

7 63. FDUTPA does not apply to claims for personal injuries, and, accordingly, Plaintiffs’  
 8 FDUTPA claim is improper and should be dismissed.

9 **Sixty-fourth Defense**

10 64. The acts or practices of which Plaintiffs complain were and are required or specifically  
 11 permitted by federal or state law. Therefore, Plaintiffs’ FDUTPA claim is barred, fails to state  
 12 a claim, and should be dismissed with prejudice.

13 **Sixty-fifth Defense**

14 65. Plaintiffs lack standing because the answering Defendants did not engage in deceptive  
 15 conduct with regard to Plaintiff or otherwise.

16 **Sixty-sixth Defense**

17 66. Plaintiffs’ claims are barred, in whole or in part, pursuant to South Carolina Code Ann.  
 18 § 15-3-20.

19 **Sixty-seventh Defense**

20 67. Defendants reserve the right to supplement their assertion of defenses as they continue  
 21 with their factual investigation of Plaintiffs’ claims.

22 **V.**

23 **PRAYER**

24 WHEREFORE, Defendants pray for judgment as follows:

25 1. That Plaintiffs take nothing from Defendants by reason of the Complaint;  
 26 2. That the Complaint be dismissed;  
 27 3. That Defendants be awarded their costs for this lawsuit;  
 28 4. That the trier of fact determine what percentage of the combined fault or other liability

Gordon & Rees, LLP  
 275 Battery Street, Suite 2000  
 San Francisco, CA 94111

1 of all persons whose fault or other liability proximately caused Plaintiffs' alleged  
2 injuries, losses or damages is attributable to each person;

3 5. That any judgment for damages against Defendants in favor of Plaintiffs be no greater  
4 than an amount which equals their proportionate share, if any, of the total fault or other  
5 liability which proximately caused Plaintiffs' injuries and damages; and  
6 6. That Defendants have such other and further relief as the Court deems appropriate.

7 June 13, 2008

8 GORDON & REES LLP

9 10 By: \_\_\_\_\_/s/

11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28  
11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28  
Stuart M. Gordon  
sgordon@gordonrees.com  
Embarcadero Center West  
275 Battery Street, 20<sup>th</sup> Floor  
San Francisco, CA 94111  
Telephone: (415) 986-5900  
Fax: (415) 986-8054

June 13, 2008

TUCKER ELLIS & WEST LLP

By: \_\_\_\_\_/s/

Michael C. Zellers  
michael.zellers@tuckerellis.com  
515 South Flower Street, Suite 4200  
Los Angeles, CA 90071-2223  
Telephone: (213) 430-3400  
Fax: (213) 430-3409

Attorneys for Defendants  
PFIZER INC., PHARMACIA  
CORPORATION, AND G.D. SEARLE  
LLC

1 **JURY DEMAND**

2 Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC, hereby demand a  
3 trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil  
4 Procedure.

5 June 13, 2008

GORDON & REES LLP

6

7 By: \_\_\_\_\_/s/

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

Stuart M. Gordon  
sgordon@gordonrees.com  
Embarcadero Center West  
275 Battery Street, 20<sup>th</sup> Floor  
San Francisco, CA 94111  
Telephone: (415) 986-5900  
Fax: (415) 986-8054

June 13, 2008

TUCKER ELLIS & WEST LLP

By: \_\_\_\_\_/s/

Michael C. Zellers  
michael.zellers@tuckerellis.com  
515 South Flower Street, Suite 4200  
Los Angeles, CA 90071-2223  
Telephone: (213) 430-3400  
Fax: (213) 430-3409

Attorneys for Defendants  
PFIZER INC., PHARMACIA  
CORPORATION, AND G.D. SEARLE  
LLC

Gordon & Rees, LLP  
275 Battery Street, Suite 2000  
San Francisco, CA 94111